



January 16, 2007

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Ms. Mary Till
Legal Advisor
Commissioner for Patents
United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Ms. Till:

This is in regard to the application for a patent term extension of U.S. Patent No. 5,510,106 filed by the Regents of the University of California under 35 U.S.C. § 156. The veterinary biologic product claimed by the patent is Fel-O-Vax® LvK/FIV vaccine (Feline Immunodeficiency-Leukemia Virus Vaccine, Killed Virus), which was assigned VS Code No. 15D5.R0. The product is manufactured by Wyeth, through its operating subsidiary Fort Dodge Laboratories, Inc.(U.S. Veterinary License No. 112).

A review of the Center for Veterinary Biologics official records indicates that this product was subject to a regulatory period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4).

The United States Veterinary Biological Product License was issued on June 23, 2003, which makes the submission of the patent term extension application on August 20, 2003, timely within the meaning of 35 U.S.C. § 156(d)(1).

Your understanding of the differences between this product and the product (Code 15A5.21) that was the subject of a previous patent term extension (5,275,813), as stated in your cover letter, is correct.

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Sincerely,

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics



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